EXHIBIT A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS,)
Plaintiff, v.) Case No. 19 CH 10481) Hon. Caroline K. Moreland
JOHNSON & JOHNSON, JANSSEN) Judge Presiding) Cal. 10
PHARMACEUTICALS, INC., ORTHO- MCNEIL-)
JANSSEN PHARMACEUTICALS, INC., JANSSEN)
PHARMACEUTICA, INC., ENDO HEALTH)
SOLUTIONS INC., ENDO PHARMACEUTICALS	
INC., TEVA PHARMACEUTICAL INDUSTRIES)
LIMITED, TEVA PHARMACEUTICALS USA, INC.,)
CEPHALON, INC., ALLERGAN FINANCE, LLC,)
ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON)
LABORATORIES, INC., MCKESSON)
CORPORATION, CARDINAL HEALTH, INC., and)
AMERISOURCEBERGEN DRUG CORPORATION,)
)
Defendants.)
MEMORANDUM OPINION AN	ND ORDER

This matter is before the Court on the various defendants' motion to dismiss the State's complaint brought pursuant to 735 ILCS 5/2-615. Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho- McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Teva Pharmaceuticals Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan Finance, LLC; Actavis Pharma, Inc.; Actavis LLC; Watson Laboratories, Inc.; Mallinckrodt plc; Mallinckrodt LLC; and SpecGx LLC (the, "Manufacturers") filed a joint motion to dismiss. McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation (the, "Distributors") filed their own joint motion to dismiss. Additionally, Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, the "Teva Defendants"); and Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, the "Actavis Defendants") filed their own motions to dismiss.

I. Background

The State of Illinois ("Illinois") alleges the each of the defendants has created a public nuisance and violated the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.*, ("CFDBPA"). The State plead a single count of public nuisance and a single count of violations of the CFDBPA against each defendant.

The State alleges that the Defendants understood the risks associated with opioids, but chose to market, promote, sell, and/or distribute opioid products in ways that led to substantial

increases in both the quantity and power of the drugs coming into Illinois." $Complaint \P 60$. "The Manufacturers promoted the expansive use of opioids, despite the lack of evidence of their benefits when used for chronic pain and in spite of their recognized risk, leading to a nationwide epidemic." $Complaint \P 104$. The Distributors are accused of failing to flag suspicious orders and put in place adequate controls to prevent the diversion of opioids from their intended recipients. The State has made the following specific allegations against the Defendants.

Janssen

The State collectively describes and refers to, Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceuticals, Inc. as "Janssen." According to the complaint, "Janssen disseminated deceptive messages about its opioid products as early as the 1990s, and has been on notice of its deceptive marketing since at least 2000. In a letter dated March 30, 2000, the FDA informed Janssen that its promotional pieces were 'false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." *Complaint* ¶ 124.

"That letter identified specific misrepresentations Janssen made that Duragesic had a low potential for abuse:

You present the claim, 'Low abuse potential!' This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, 'Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine.' Therefore, this claim is false or misleading." *Complaint* ¶ 125.

"In 2001, Janssen was advised by its own hired scientific advisory board that many of the marketing messages Janssen used to promote opioids in general, and Duragesic specifically, were misleading and should not be disseminated. Specifically, the advisory board advised Janssen not to market opioids, including Duragesic, using messages related to abuse or with claims about supposedly low abuse potential." *Complaint* ¶ 126. Further allegations of false or misleading claims, statements and marketing by Janssen are plead in paragraphs 127-249 of the complaint.

Endo

In the Complaint, Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are grouped together as "Endo." The States complaint pleads a 70 year involvement in the opioid industry by the Endo Entities. According to the complaint, "In 1950, Endo launched an oxycodone and aspirin combination product called Percodan. In 1971, it launched Percocet, an immediate release oxycodone and acetaminophen combination product. Endo subsequently launched new

strengths of Percocet in 1999 and 2001." *Complaint* ¶ 250. "In 1959, Endo also launched Numorphan, an immediate release oxymorphone product. Oxymorphone is the same active ingredient in Opana ER. Endo voluntarily withdrew Numorphan from the market in 1982, due, in part, to reports that people were abusing the drug via injection." *Complaint* ¶ 251. In 2006 Endo launched Opana ER "and subsequently received FDA approval for and transitioned to a crush resistant formulation of Opana ER in 2012. Endo sought to make Opana ER its 'flagship brand.'" *Complaint* ¶ 251.

The Complaint describes how Endo, in an effort to increase sales of Opana:

[C]reated a presentation, "Better the Devil you Know... Inspiring Physicians to Do the Right Thing with Opana ER." The presentation recommended messages for Opana ER that would help physicians "overcome their fear" of prescribing opioids and "do what's right." The presentation recommended positioning Opana as the "responsible" opioid that was "less attractive to drug seekers" and caused "less euphoria." These deceptive messages were advanced by Endo for years. *Complaint* ¶ 257.

Endo's sales representatives conveyed these misrepresentations directly to health care providers, stating in sales calls that Opana ER had, for instance, "less abuse potential," "low incidence of euphoria," and was "very resistant to adulteration" and "not prone to abuse." Endo sales representatives sought to capitalize on health care providers' concerns regarding the risk of opioid abuse by, for instance, asking doctors, regarding Opana ER, "[h]ow willing would you be to consider adding an opioid to your rotation that you possibly wouldn't have to worry so much about?" *Complaint* ¶ 258.

Later the State alleges that when the patent protection for Opana ER was set to expire, Endo created and attempted to market a new formula of Opana that they claimed was more resistant to abuse even though there was a lack of any scientific evidence for such a claim. *See* Complaint ¶¶ 262-272. The Complaint goes on to detail how Endo caused allegedly misleading advertising material regarding Opana to be distributed to the market place:

Endo created a 2008 brochure titled "Taking a Long-Acting Opioid," that likewise told consumers that "patients treated with prolonged opioid medicines usually do not become addicted" and that "[t]aking opioids for pain relief is NOT addiction." *Complaint* ¶ 287.

The same misleading message was contained in a guide Endo developed for caregivers called Living with Someone with Chronic Pain. This caregiver's guide stated that "[m]ost healthcare providers who treat people with pain agree that most people do not develop an addiction problem" when taking opioids. The guide was available, including to Illinois consumers, on the opana.com website as well as in brochure format. *Complaint* ¶ 288.

Endo also trained its sales representatives to disseminate these misleading messages. For instance, a 2010 training guide instructed sales representatives that "long-term opioid use can induce physical dependence and may induce tolerance to therapy" and that "[n]one of these physiological phenomenon cause addiction." The same training guide told Endo's sales representatives that it was "false" that "[a]ddiction to opioid medications is very common." *Complaint* ¶ 290.

The complaint goes on at length for an additional 80 paragraphs about various allegedly false, misleading, and deceptive statements that Endo knowingly made in its efforts to profit off of its opioid business. *See Complaint* ¶¶ 291-370.

Teva

The State alleges that since "2011, Teva Ltd., Teva USA, and Cephalon, Inc. have worked together closely to market and [s]ell Cephalon products in the United States." *Complaint* ¶ 371. These products include Actiq and Fentora. *Id.* Teva Ltd. Acquired Cephalon, Inc. in 2011. *Id.* Teva Ltd., Teva USA, and Cephalon, Inc. are collectively referred to as "Teva" in the State's complaint and in the order.

According to the Complaint "Both Actiq and Fentora were marketed by Teva as a new category of 'rapid onset opioids' or ROOs, which Teva sought to differentiate from other short-acting opioids based on their rapid onset of analgesia." *Complaint* ¶ 375. According to the Complaint Actiq and Fentora "are approved only for treatment of breakthrough cancer pain in opioid-tolerant patients already on around-the-clock treatment for pain." *Complaint* ¶¶ 372, 385-86. The State alleges that Teva:

disseminated numerous unfair, deceptive and unsubstantiated claims regarding opioids generally and Teva's opioid products specifically, including that opioids have minimal addiction risk, that signs of addiction are actually just "pseudo addiction" and should be addressed by prescribing even more or stronger opioids, and that opioids improve patients' quality of life and function.

Teva advanced these and other misleading concepts to doctors and patients, including in Illinois, in order to encourage the use of its opioids at higher doses over longer periods of time, and thereby maximize Teva's bottom line. *Complaint* ¶¶ 378-79.

Teva used direct detailing by its sales representatives, speaker programs, continuing medical education programs, and other methods to promote and encourage the use of its extremely powerful opioid products, Actiq and Fentora, for treatment of non-cancer pain. *Complaint* ¶ 388.

In November 2000, Teva created a "Master Plan" for Actiq which included "expanding the target physician and patient population to allow penetration of the broad chronic pain market. This should be the driver of all

activities associated with Actiq in 2001 – marketing, clinical, regulatory and operations." *Complaint* ¶ 389.

According to the Complaint Teva knew many of its claims regarding Actiq and Fentora were untrue and had received pushback from the FDA. For Example:

By September 2007, just a year after Fentora's approval, concerning reports of serious adverse events, including deaths, in patients taking Fentora prompted both a "dear healthcare professional" letter to be sent by Teva and a public health advisory to be issued by the FDA, warning healthcare professionals of the dangers of Fentora, including off-label prescribing. The FDA public health advisory makes clear that "deaths occurred in patients who did not have cancer and/or were not opioid tolerant." *Complaint* ¶ 408.

In February 2008, an internal audit of Teva's sales and marketing practices found that the company's marketing documents "may give regulators the incorrect appearance that off-label promotion is occurring and being planned," that "Fentora key planning documents did not clearly delineate between future strategic goals versus targets that represent current or near term anticipated labels," and that non-complaint speaker programs "may be taking place." *Complaint* ¶ 410.

In March 2009, the FDA sent Teva a warning letter citing concerns over Teva's online marketing for Fentora. The letter addressed materials that failed to disclose the risks associated with the drug. The letter also addressed marketing that the FDA called "misleading" because it failed to convey the full indication for Fentora and instead dangerously suggested that "Fentora is appropriate for all cancer patients without breakthrough pain" instead of only opioid-tolerant cancer patients. *Complaint* ¶ 413.

The Complaint also alleges that Teva mislead patients about the risks of taking Actiq and Fentora. *See Complaint* ¶¶ 425-29. Teva also allegedly mislead doctors about addiction risk to their patients. *See Complaint* ¶¶ 440-44. Teva made these claims without any scientific backing. *See Complaint* ¶ 444. Teva also published false claims about the addictive qualities of Actiq and Fentora:

Teva widely disseminated the conclusion that for 136 of 197 or 69% of study participants "the final maintenance dose of Fentora was the same as the initial dose" and even explicitly claimed that for 69% of patients "the final dose of FENTORA after 12 months was the same as the initial dose." (Emphasis added). Teva made these claims for years in materials it disseminated to health care providers and patients, directly and through its speaker programs, as well as in its internal training for its sales representatives.

Teva's claims were misleading because, in fact, only 34 of the 197 patients that began the 12-month maintenance portion of the study, or approximately 17%, actually finished the full 12 months or at least 360 days.

In addition, Teva ignored or downplayed the fact that many study patients were taking more and more doses of Fentora per day. Thus, even if each individual dispensed dose remained the same strength, this meant many study participants' daily dose, or micrograms of Fentora per day, were increasing. $Complaint \P 484-86$

Allergan

The State groups defendants Allergan Finance, LLC, Actavis Pharma, Inc., Actavis LLC, and Watson Laboratories, Inc. collectively as "Allergan." *Complaint* ¶ 31. According to the complaint Allergan made its misleading statements in relation to its drug Kadian which it purchased from Alpharma. For example, "Allergan promoted the idea of 'pseudo addiction' even though there was no competent scientific evidence supporting this concept." *Complaint* ¶ 534. Allergan also published material and trained its sales force "that tolerance and dependence do not indicate addiction; rather, they are expected consequences of opioid use over a length of time, and rarely prevent effective pain relief." *Complaint* ¶ 539. While in fact:

CDC has explained that "patients who do not experience clinically meaningful pain relief early in treatment (i.e. within 1 month) are unlikely to experience pain relief with longer-term use,"93 thus advising that physicians should consider discontinuing opioid use for those patients who are exhibiting behaviors that indicate ineffective pain relief, not increasing their doses. Complaint ¶ 538.

The complaint also details the extent that Allergen attempted to dissuade doctors from the risk of addiction to its drug and instead described increasing need for a greater dose in patients as mere tolerance. Complaint ¶¶ 539-44. Plaintiff alleges that, "[c]ontrary to Allergan's representations, up to 26% of opioid users in primary care settings and as many as 30% or even 40% of long-term opioid users experience problems with addiction. Allergan's representations that the risk of addiction is low were misleading." Complaint \P 545.

Allergan also allegedly made misleading statements regarding the abuse deterrent formulation of Kadian. Claiming, without FDA approval, that:

The "unique pharmaceutical formulation of Kadian may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and that the "pharmacokinetics of morphine following single doses of Kadian are an important consideration in assessing the abuse and dependence potential" because "the subjective effect of euphoria, which is possibly related to

rapid delivery of high peak plasma levels of morphine sulfate, may not be noted following a dose of Kadian." *Complaint* ¶ 550-51.

Mallinckrodt

Plaintiff's complaint collectively refers to Mallinckrodt PLC, Mallinckrodt LLC and SpecGx LLC as ("Mallinckrodt"). *Complaint* ¶ 937. Mallinckrodt makes the following branded opioid products "Exalgo, Xartemis XR, Roxicodone, and Methadose." *Complaint* ¶ 940. According to the complaint, between 2006 and 2012, Mallinckrodt was the single largest supplier of prescriptions opioids in the U.S." *Complaint* ¶ 942.

Mallinckrodt is alleged to have made the following misleading claims regarding its opioid products:

Mallinckrodt downplayed the risks of addiction from Exalgo in its "Patient Guide." To allay patients' fears about opioid addiction, in a section titled "The Difference Between Dependence and Addiction," Mallinckrodt reassured patients that even though they "may worry about addiction" when taking a strong pain medication, that "[j]ust because you take an opioid, doesn't mean you will become addicted." The brochure went on to emphasize physical dependence and withdrawal as conditions that are completely separate from addiction. *Complaint* ¶ 948.

Mallinckrodt knew that consumers would be persuaded by the messaging in its "Patient Guide" because it conducted extensive consumer surveys in August 2012. Mallinckrodt conducted focus groups with patients taking opioids for chronic pain, concluding that "The Difference Between Dependence and Addiction' is welcomed information among patients. They find comfort in reading that the use of chronic pain medication does not mean being addicted to the medication," and that patients "feel reassured by the idea that the dependence they have on their medication does not mean they are addicted to it." *Complaint* ¶ 949.

Mallinckrodt's market research even showed this messaging caused confusion in consumers, noting that one participant stated: "I'm wondering if you can become addicted or not addicted. It's not saying you will become addicted, but it's not saying you won't either." Another participant noted: "Knowing I could take [Exalgo] and not become an addict would be very reassuring, and I'd feel good about that." *Complaint* ¶ 950.

Mallinckrodt allegedly made misleading claims to doctors regarding the risk of addiction from its products that it knew were untrue. *See Complaint* ¶¶ 975-983. Mallinckrodt allegedly marketed its drugs as "tamper resistant" and "abuse deterrent" which was untrue. *Complaint* ¶¶ 984-1000. Mallinckrodt also allegedly made false claims about the benefits of taking its drugs.

See Complaint ¶¶ 1001-18. The Complaint also alleges that Mallinckrodt marketed its deceptive and untrue messages directly to Illinois consumers. See Complaint ¶¶ 1019-36.

Distributors

The State names three distributors, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation, in its Complaint. Each allegedly failed in its duty to properly examine and report suspicious orders of opioid medications.

II. Motion to Dismiss

"A section 2-615 motion to dismiss challenges the legal sufficiency of the complaint." Yoon Ja Kim v. Jh Song, 2016 IL App (1st) 150614-B ¶ 41. Motions brought under Section 2-615 do not raise affirmative factual defenses. Id. Rather, "[a]ll well-pleaded facts and all reasonable inferences from those facts are taken as true. Where unsupported by allegations of fact, legal and factual conclusions may be disregarded." Kagan v. Waldheim Cemetery Co., 2016 IL App (1st) 131274 ¶ 29. "In determining whether the allegations of the complaint are sufficient to state a cause of action, the court views the allegations of the complaint in the light most favorable to the plaintiff. Unless it is clearly apparent that the plaintiff could prove no set of facts that would entitle him to relief, a complaint should not be dismissed." Id.

III. Analysis

The State has plead two counts against each of the defendants. One for creating a public nuisance, and one for violating the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.*, ("CFDBPA").

PUBLIC NUISANCE

The Illinois Supreme Court has defined "four distinct elements of a public nuisance claim: the existence of a public right, a substantial and unreasonable interference with that right by the defendant, proximate cause, and injury." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 369 (2004). Both the Distributors and the Manufacturers argue that the Illinois Supreme Court's decision in *City of Chicago v. Beretta U.S.A. Corp.*, precludes as a matter of law, a cause of action for public nuisance for the types of conduct alleged against them in the complaint. *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351 (2004). The State argues that *Beretta* is distinguishable because they are asserting the "public right of public health, with which the Defendants unlawfully interfered."

In *Beretta*, the City of Chicago ("Chicago") and Cook County brought public nuisance claims against "18 manufacturers, 4 distributors, and 11 dealers of handguns. *Id.* Chicago sought "compensation for the costs of emergency medical services, law enforcement efforts, the prosecution of violations of gun control ordinances, and other related expenses." *Id at* 356. Cook County sought "compensation for the costs of treatment of victims of gun violence and the costs of prosecutions for criminal use of firearms, including the expenses associated with providing

defense counsel to those accused of gun crimes." *Id.* Both the City and County sought "punitive damages and permanent injunctive relief to abate the alleged public nuisance." *Id.*

In their pleadings the City and County alleged that the "defendants [were] put on notice of the 'crime-facilitating consequences of their conduct,' by virtue of the process used by the United States Bureau of Alcohol Tobacco and Firearms (ATF) to trace firearms recovered by federal, state, and local law enforcement agencies." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 358 (2004). Chicago and Cook County specifically alleged that the defendants sold "firearms even when they know or should know that the firearms will be used or possessed illegally in Chicago." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 359 (2004). Further, the City and County both alleged that the firearms manufacturers specifically include features that would be desirable by criminals and serve no useful purpose for legal uses of firearms. *Id* at 361.

Ultimately, the Supreme Court sustained the trial court's dismissal of the public nuisance claims. In rendering their decision, the Illinois Supreme Court acknowledged "[t]he tragic personal consequences of gun violence are inestimable. The burdens imposed upon society as a whole in the costs of law enforcement and medical services are immense." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 355 (2004). However, in denying Chicago and Cook County's claims, the Supreme Court found that the *Beretta* plaintiffs' claims failed to plead an unreasonable interference with a public right and a lack of proximate cause of defendants' conduct to the plaintiff's alleged injuries. Additionally, based on these failures the Court declined to create a new public right, which the Supreme Court identified as the individual right to be free from the criminal or illegal acts of other individuals. 213 Ill. 2d, 374-75. The Supreme Court also ruled that monetary damages were unavailable to Chicago and Cook County.

Much like the *Beretta* Court, this Court cannot deny the tragic consequences to Illinois residents of the conduct allegedly committed by the Defendants. *See* Complaint. ¶¶ 43-60. Including over 18,000 overdose deaths, *Complaint* ¶ 81, 32,000 babies born addicted to opioids, *Complaint* ¶ 46, and over half a billion dollars in annual expenses treating opioid addiction. *Complaint* ¶ 51. However, also like the Beretta Court, this Court finds that there is no public nuisance caused by the Defendants' conduct.

Public Right

The "first element that must be alleged to state a claim for public nuisance is the existence of a right common to the general public. Such rights include the rights of public health, public safety, public peace, public comfort, and public convenience." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 370-71 (2004). The State alleges that the public has a right to "health, safety, peace, and comfort" which the Manufacturer Defendants have violated by unlawfully disseminating deceptive or misleading promotional messages and materials in Illinois despite knowing that opioids carried serious risk of addiction, injury, overdose, and death; failing to disclose material facts; and failing to monitor and report the potential abuse and diversion of opioids in Illinois. The States allegations against the Distributers are similar.

The Supreme Court in *Beretta* discussed the many dangerous uses of otherwise legal products which the state legislature passed laws banning. It ultimately concluded that a public right to be free from the threat that others "may defy these laws would permit nuisance liability to be imposed on an endless list of manufacturers, distributors, and retailers of manufactured products." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 375 (2004). The *Beretta* Court likened Chicago's and Cook County's allegations as a mass assertion of an individual right to be free from the illegal conduct of others. *Id* at 371.

The State argues that their claims are distinct from those in *Beretta* because they involve allegations of illegal and misleading conduct occurring in Illinois and have nothing to do with the illegal actions of 3rd parties. The State alleges that the Manufacturer Defendants violated the Illinois Controlled Substances Act and The Illinois Consumer Fraud and Deceptive Business Practices Act in causing an increase in the amount of opioids used and abused in Illinois. The State alleges that the Distributer Defendants had a duty under both the Controlled Substances Act (CSA), 21 U.S.C. §§ 823(b)(1) and 1307.74(b) and the Illinois Controlled Substances Act 720 ILCS 570/100 to prevent diversion of their products. The State links their failure in their statutory duty to prevent the diversion of prescription opioids to the epidemic abuse of prescription opioids. This distinction however does not change the nature of the claim the State seeks to assert in their public nuisance claim.

The only other Illinois Case cited by the State in support of the existence of a public right is *Lewis v. Lead Indus. Ass'n* 342 Ill. App. 3d 95 (1st Dist. 2003)¹. In *Lewis* the appellate court upheld the general notion that there is a common right to health and safety. *Id* at 107. However, that notion is not disputed. What is disputed is the actual nature of the right being asserted by the State.

In *Beretta*, the Illinois Supreme Court rejected "a common right to be free *from conduct* that creates an unreasonable jeopardy to the public's health, welfare and safety, and to be free *from conduct* that creates a disturbance and reasonable apprehension of danger to person and property." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 371 (2004). Here, like *Beretta* it appears that the state is attempting to hold a manufacturer and distributor of a legal product responsible for the misuse of its products by others.

Unreasonable Interference

"Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following: (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public

¹ Both parties have cited many trial level court orders upholding or dismissing similar claims. The Court in rendering its decision has not considered these cases. Many of them are simply deny or grant motions to dismiss

without any reasoning given. Few if any look at Illinois law specifically. The fact that more cases were decided one way or another is immaterial. The Court does not make decisions based on the weight of the paper one side or the other presents, or based on the number of other judges who may or may not be ruling on similar issues. It looks at the facts and pleadings put before it as they relate to Illinois law.

convenience, or (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or (c) whether the conduct is *of a continuing nature* or has produced a permanent or long-lasting effect, *and*, as the actor knows or has reason to know, has a *significant effect* upon the public right." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 375-76 (2004) (*citing* Restatement (Second) of Torts § 821B (2) (1979)).

A close look at the allegations laid out in the complaint which the Court in part repeated *supra* in its background section supports the notion that the Manufacturer Defendants did their level best to promote the use of opioids using materials that were allegedly knowingly false and not in full compliance with FDA regulation. These allegations do appear to be distinguishable from that wholly lawful conduct discussed in *Beretta*. *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 375-94 (2004). In *Beretta*, there was no mention that the defendants' conduct would be in anyway illegal or subject to other liability in the locality where it occurred. However, the Court does not find that the State as adequately laid out a public right in this case.

As to the Distributer Defendants the Court does not find that the allegations establish unreasonable interference with any right relating to public health. The Distributor Defendants put no false information in the stream of commerce. At best, the State alleges issues with administrative compliance, which does not seem to rise to the level of conduct prescribed by administrative regulation. The Court agrees with the logic of *Beretta* that if the distributors did something wrong in failing to report suspicious orders it should be handled at the administrative level. *Id* at 387-88.

Proximate Cause

The Third element of a claim for public nuisance is proximate cause, which is broken down to cause in fact and legal cause. *Lee v. Chicago Transit Authority*, 152 Ill. 2d 432, 455 (1992). "Cause in fact can only be established when there is a reasonable certainty that a defendant's acts caused the injury." *Id.* Legal cause is a question of foreseeability or remoteness *Id; City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 395-96 (2004). Proximate cause is generally a question of fact. *Lee*, 152 Ill. 2d at 455). However, the lack of proximate cause may be determined by the court as a matter of law where the facts alleged do not sufficiently demonstrate both cause in fact and legal cause. *Harrison v. Hardin County Community Unit School District No. 1*, 197 Ill. 2d 466, 476, (2001).

In *Beretta*, the Supreme Court held that Chicago and Cook County had adequately plead the defendants were the cause in fact of the injuries they allegedly suffered. *Beretta*, 213 Ill. 2d 403-04. Here, because this Court sees the *Beretta* defendants and the Manufacturer and Distributor Defendants sitting similarly situated it cannot rule out the possibility that a finder of fact could find them responsible for the State's injuries.

However, like the *Beretta* court, this Court finds that there are too many instrumentalities between the conduct of the Manufacturer and Distributor Defendants to the alleged harm. The plaintiff's in *Beretta* plead that defendants intended their products to illegally enter the Chicago market. This is similar to the wealth of intentionally misleading conduct alleged against the Manufacturer and Distributor Defendants in this case. The fact is that individual pharmacies, doctors, and patients all have to behave poorly to generate the harms alleged by the State. Therefore, the State has failed to establish proximate cause.

Injury

Because the Court is dismissing the public nuisance claims against all the Defendants it does not need to consider the applicability of the remedies plead or the injuries alleged.

CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

Both the Manufacturer Defendants and the Distributor Defendants make two argument about why the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.*, ("CFDBPA") claims should be dismissed: 1) the State has failed to plead any unfair conduct; and 2) the claims against them fall into a federal safe harbor provision or are otherwise preempted by Federal Law. Here the Court agrees that the State has failed to allege any unfair conduct against the Distributor Defendants, but find that the State has adequately plead a CFDBPA claim against all of the Manufacturer Defendants.

Unfair Conduct

Both the Manufacturer Defendants and the Distributor Defendants argue that the claims against them fail because the State has not alleged any unfair conduct as defined by the CFDBPA. Illinois Courts have noted that:

In determining whether a given course of conduct or act is unfair, we observe the Consumer Fraud Act mandates that "consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5(a) of the Federal Trade Commission Act." 815 ILCS 505/2 (West 1992). The United States Supreme Court in *Federal Trade Comm'n v. Sperry & Hutchinson Co.*, 405 U.S. 233, 31 L. Ed. 2d 170, 92 S. Ct. 898 (1972), cited with approval the published statement of factors considered by the Federal Trade Commission in measuring unfairness. *Sperry*, 405 U.S. at 244 n.5, 31 L. Ed. 2d at 179 n.5, 92 S. Ct. at 905 n.5. These factors are (1) whether the practice offends public policy; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers. *Sperry*, 405 U.S. at 244 n.5, 31 L. Ed. 2d at 179 n.5, 92 S. Ct. at 905 n.5. *Robinson v. Toyota Motor Credit Corp.*, 201 Ill. 2d 403, 417-18 (2002)

In discussing whether the all of the *Sperry* factors must be met, the Illinois Supreme Court adopted the holding of the Connecticut Supreme Court in *Cheshire Mortgage Services*, *Inc. v. Montes. Robinson v. Toyota Motor Credit Corp.*, 201 Ill. 2d 403, 418 (2002). The

Cheshire Court held that "In interpreting that state's unfair trade practices statute, all three of the criteria in Sperry do not need to be satisfied to support a finding of unfairness. Cheshire Mortgage Services, Inc. v. Montes, 223 Conn. 80, 106, 612 A.2d 1130, 1143 (1992). The Cheshire court cited with approval and quoted the Statement of Basis and Purpose, Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures, 43 Fed. Reg. 59,614, 59,635 (1978), as follows "'All three criteria do not need to be satisfied to support a finding of unfairness. A practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three." Cheshire, 223 Conn. at 106, 612 A.2d at 1143-44.

Here, the Court finds that the alleged actions, marketing, and other statements made by the Manufacture Defendants constitute potential violations of the CFDPA. However, the Court finds that the State's allegations against the Distributor Defendants are insufficient to fall under *any* of the *Sperry* factors.

Additionally, an action brought by the Attorney General under section 2 of the CFDPA does not require that "any person has in fact been misled, deceived or damaged" *Oliveira v. Amoco Oil Co.*, 201 Ill. 2d 134, 149 (2002) (*quoting* 815 ILCS 505/2). Therefore, there is no issue with the States standing to raise these claims.

Federal Preemption and CFDBPA Safe Harbor

In evaluating whether federal law pre-empted a lawsuit against branded drug manufacturers:

"[P]re-emption is a demanding defense," and the defendant drug company has the burden of demonstrating that it applies. *Wyeth*, 555 U.S. at 573 ("Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements."); see also *Wyeth*, 555 U.S. at 581 ("Wyeth has not persuaded us."). "Congress enacted the FDCA to bolster consumer protection against harmful products," not to lessen it. *Wyeth*, 555 U.S. at 574. The United States Supreme Court observed: "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." *Wyeth*, 555 U.S. at 574, 574 n.7 (observing that witnesses testified before the Senate that a federal "right of action was unnecessary because common-law claims were already available under state law").

Thus, the defendant drug company bears the burden of demonstrating that these state rights are federally preempted.

"'[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 555 U.S. at 574. When Congress enlarged the FDA's powers to

protect the public and ensure the safety and effectiveness of drugs, Congress included a statement of its intent with respect to state law: "No provision of this Act nor any amendment made by it shall be construed as indicating any intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together." (Emphasis added.) Pub. L. 89-74, § 10, 79 Stat. 235 (1965); Wyeth, 555 U.S. at 567 (discussing Congress's intent and purpose in the 1962 amendment).

Thus, to satisfy its burden, a defendant drug company must show a direct and positive conflict that cannot be reconciled. *Guvenoz v. Target Corp.*, 2015 IL App (1st) 133940, ¶¶ 45-48.

Similarly, in *Price v. Philip Morris, Inc.*, when considering whether federal rules preempted state lawsuits against cigarette manufacturers the Illinois Supreme Court held:

We reject [Philip Morris USA] PMUSA's assertion that section 10b (1) operates to bar plaintiffs' claim merely because PMUSA may have been in compliance with applicable federal law. The plain language of section 10b (1) requires that two separate conditions be present before a claim is barred. First, a regulatory body or officer must be operating under statutory authority. In this case, the first condition is met. The FTC operates under the authority of the FTC Act (15 U.S.C. § 45(a) (2000)), and the Labeling Act (15 U.S.C. § 1331 et seq. (2000)), to regulate the packaging and advertising of cigarettes. Second, liability under the Consumer Fraud Act is barred by section 10b (1) only if the action or transaction at issue is "specifically authorized by laws administered" by the regulatory body. 815 ILCS 505/10b (1) (West 1998). As we explain in detail, below, PMUSA's mere compliance with the rules applicable to labeling and advertising is not sufficient to trigger the exemption created by section 10b (1). *Price v. Philip Morris, Inc.*, 219 Ill. 2d 182, 240-41 (2005)

Whether specific terms are deceptive goes to the merits of the fraud claim, not to the threshold question of exemption under section 10b(1) of the CFDBPA, under which the real issue is whether the FDA has specifically authorized the defendants to market their products as alleged in the complaint. *Price v. Philip Morris, Inc.*, 219 Ill. 2d 182, 241 (2005)

In this case Federal Preemption cannot apply because the State has specifically alleged that each and every Manufacturer Defendant made statements that the FDA allegedly disagreed with and otherwise failed to approve. This is not, as the Manufacturer Defendants, suggest a situation where the statements constituting the unfair business practice were part of the label of the product they were marketing or otherwise approved by the FDA.

WATSON LABORATORIES ACTIVIS LLC AND ACTAVIS PHARMA

Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, the "Actavis Defendants") seek to have the counts dismissed against them for a separate reason. Namely, that they only sold generic opioids and therefore were not responsible for any of the marketing statements made by the other Manufacturer Defendants. This argument fails for two reasons. First, the State defined these entities as Allergan and made numerous and specific allegations relating to their conduct promoting their *branded product* Kadian. Second, under a 2-615 motion the contradictory issues raised in the motion cannot be considered by this court. For these reasons the Actavis Defendants' separate motion is denied.

CEPHALON & TEVA PHARMACEUTICALS

Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, the "Teva Defendants") argue that the claims against them should be dismissed because they make a type of short acting opioid medication that has special FDA regulation. This argument does not defeat the allegations made against the Teva Defendants. The State specifically alleged that they made claims that were not approved by the FDA and were in fact specifically told to stop making them. At the pleadings stage the fact that Fentora and Actiq have additional regulations beyond that of the drugs produced by the other Manufacturer Defendants does not defeat the CFDBPA claims plead by the State.

Conclusion

- All claims against MCKESSON CORPORATION, CARDINAL HEALTH, INC., and AMERISOURCEBERGEN DRUG CORPORATION, are dismissed with prejudice. Pursuant to Illinois Supreme Court rule 304(a) there is no reason to delay enforcement or appeal of this order.
- 2. Counts Eight, Nine, Ten, Eleven and Sixteen are dismissed with prejudice.
- 3. This matter is set for status on February 5, 2021 at 11:00 AM.
- 4. This matter is stayed as to the Mallinckrodt Defendants due to the automatic stay in bankruptcy

Judge Carolina Kura Moreland

JAN 08 2021

Circuit Court - 2033

Entered:

Judge Caroline Kate Moreland